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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/299,562	04/27/1999	LAJOS HEGEDUS	3347-101P	3425

26646 7590 12/18/2001  
KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER
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WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/18/2001

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/299,562

Applicant(s)

HEGEDUS ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-37 and 42-94 is/are pending in the application.
- 4a) Of the above claim(s) 24-29, 91 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-37, 42-90, 93-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 24-37 and 42-94 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The examiner in charge of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Sandra Wegert in Group Art Unit 1647.

### **DETAILED ACTION**

#### ***Status of Application, Amendments, and/or Claims***

The amendment filed 30 September 2001 (Paper No. 17) has been entered. Claims 1-23 and 38-41 have been cancelled. Claims 24-29 were withdrawn by the examiner (Paper 10). Claims, 30-37, 42-90 and 93-94 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly submitted claims 91 and 92 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: it does not read upon the Inventive Group elected by the applicant in Paper 15. Claims 91 and 92 are related to the claimed Invention as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods recited can be used to deliver other compositions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91 and 92 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 30-37, 42-90 and 93-94 are currently under examination.

### ***Withdrawn Objections and/or Rejections***

The requirement for an updated filing history to be inserted into the specification as set forth at p. 2 of the previous office action (Paper No. 10, 16 March 2000) is withdrawn in view of Applicant's amendment providing an update of the filing history (Paper No. 17, 4 Oct. 2001).

The rejection of Claims 1-9 under 35 USC §102(b) or alternatively, 103(a) as being anticipated by Mitsuharu (JP 58-216126, 1983) is withdrawn because applicant cancelled claims 1-9, and because of the explanation by applicant that the scope of the *solubilities* of the components of the Instant Invention do not overlap with the solubilities reported by Mitsuharu (JP 58-216126, 1983).

The rejection of Claims 1-10 under 35 USC §102(e) as being anticipated by Desai (US 5,916,596) as set forth at pp. 9-10 (Paper No. 10), is withdrawn based on explanations from applicant as to how the composition recited in the *Desai* Patent is not overlapping in scope with that in the Instant Application, and because the *Desai* Patent claims the methods rather than the composition.

***Maintained Rejections/Objections***

The rejection of Claims 30-37 under 35 USC 112, first paragraph, set forth at pp. 4-5 of the previous office action (Paper No. 10) is maintained. The specification, while being enabling for a composition comprising paclitaxel and albumin, for example, is not enabling for the many compositions encompassed by the claims. Claims 30-37, 42-90 and 93-94 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 3/16/00. Applicants have amended the claims without removing references such as "a water-soluble product" and "substantial binding affinity to plasma proteins", that would limit the *scope* of the claimed invention. While the amendments do provide some limitations as far as, for example, solubility, the breadth of the claims is still large enough to encompass numerous compositions comprising the insoluble drug and blood protein.

The rejection of Claims 30-37 under 35 USC 112, second paragraph, set forth at pp. 6-7 of the previous office action (Paper No. 10) is maintained. The claims are rendered indefinite by reciting "*substantial binding affinity*", which is vague and confusing. Claims 42-80 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of Paper 10.

The rejection of Claims 30-31 and 36 under 35 USC §102(b) or alternatively, 103(a) as being anticipated by Satoh (EPO 0326618, 1988) is maintained for the reasons set forth at pp. 8-

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11 (Paper No. 10) and because amended claims still encompass many products with the recited characteristics anticipated by Satoh. The Instant Claims make no mention of properties that distinguish the claimed compositions from those disclosed in the EPO 0326618 patent (Satoh, 1988). Claims 30, 42-90 and 93-94 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of Paper 10.

***New Rejections/Objections***

Claims 30, 32-37, 50-56, 58, 61-78, 81, 82, 85-90 and 93-94 are objected to because they recite or encompass non-elected inventions.

Conclusion: Claims 30-37, 42-90, and 93-94 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

12/17/01

*Gary L. Kunz*  
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